K091056

5. 510(k) Summary

JUN 23 2009

510(k) Summary of Safety and Effectiveness

Company Name:	Rhythmlink International, LLC 1256 First Street South Extension Columbia, SC 29209 Phone: 803-252-1222 FDA Registration #: 1067162 Owner Operator #: 9052354
Official Contact Person:	James M. Mewborne Director of Engineering and Regulatory Affairs Rhythmlink International, LLC 1256 First Street South Extension Columbia, SC 29209 Phone: 803-252-1222 ext. 12 Email: jmewborne@rhythmlink.com
Summary Date:	April 9, 2009
Device Identification:	**Proprietary Device Name:** Rhythmlink Disposable Monopolar EMG Needle (Trade names have not been finalized at this time) **Generic Device Name:** Diagnostic Electromyograph Needle Electrode **Regulatory Class:** Class II **Classification Name:** 21 CFR §890.1385, Diagnostic Electromyograph Needle Electrode This device has not been previously submitted to the FDA.
Predicate Device(s):	510(k) Number: K071185 Manufacturer: Ambu® Trade Name: Neuroline Disposable Monopolar Needle Electrode Product Code: IKT

Device Description:	Rhythmlink Disposable Monopolar EMG Needle is a device intended for recording muscle activity during electromyography (EMG) procedures. The device consists of an insulated monopolar needle, needle hub, connector (solderless crimped connection), and plastic needle cover. The monopolar needle is made of medical grade stainless steel and is available in three lengths. The entire needle is coated with Teflon (PTFE), except for the recording tip, to insulate the needle and reduce friction upon insertion. The solderless crimped connection consists of a gold-plated brass tube 1mm in thickness, crimped onto the isolated needle. The connection is covered with a needle hub made of black polyethylene molding. The plastic needle cover is made of polyethylene. The device is available in seven different needle sizes. The needles are available in 0.32 to 0.57mm in diameter and are available in 15 to 75mm lengths. The needle is intended to record muscle activity during EMG procedures, and the needle hub is designed to be held by the user to secure the needle in the recording site. The solderless crimped connection secures the needle to the end of the leadwire. With the exception of the needle length, needle diameter, and leadwire length, the components and their dimensions are consistent throughout the product line, and these material and dimensional specifications are outlined in the product drawing under **Device Description**.
Indications for Use:	Recording muscle activity for Electromyography (EMG) applications. For single patient use only.

This concludes the 510(k) summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2009

Rhythmlink® International, LLC
c/o James M. Mewborne
Director of Engineering and Regulatory Affairs
1256 First Street South Extension
Columbia, SC 29209

Re: K091056
Trade/Device Name: Rhythmlink Disposable Monopolar EMG Needle
Regulation Number: 21 CFR 890.1385
Regulation Name: Diagnostic Electromyograph Needle Electrode
Regulatory Class: II
Product Code: IKT
Dated: April 9, 2009
Received: April 13, 2009

Dear Mr. Mewborne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): Pending K091056

Device Name: Rhythmlink Disposable Monopolar EMG Needle

Indications For Use: Recording muscle activity for Electromyograph (EMG) applications. For single patient use only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JOE HUTTER

(Division Sign-Off)
Division of Ophthalmic and Ear,
Nose and Throat Devices

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